

FORM PTO-1390 (REV. 11-2000)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				3868-0103P	
				U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 09/280211	
INTERNATIONAL APPLICATION NO.		INTERNATIONAL FILING DATE		PRIORITY DATE CLAIMED	
PCT/EP00/04588		May 20, 2000		June 2, 1999	
TITLE OF INVENTION SUBSTRATE SECTIONS HAVING INCREASED STORAGE STABILITY DURING THEIR STORAGE IN A BAG PACKAGE, AND PROCESS FOR THEIR MANUFACTURE					
APPLICANT(S) FOR DO/EO/US SCHUMANN, Klaus; THEOBALD, Frank; VON FALKENHAUSEN, Christian					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).</p> <p>4. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p> a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). WO 00/74660 A3</p> <p> b. <input type="checkbox"/> has been transmitted by the International Bureau.</p> <p> c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p> a. <input checked="" type="checkbox"/> is transmitted herewith.</p> <p> b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4)</p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p> a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</p> <p> b. <input type="checkbox"/> have been transmitted by the International Bureau.</p> <p> c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p> d. <input checked="" type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input checked="" type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>					
Items 11. to 20. below concern document(s) or information included:					
<p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98, Form PTO-1449(s), and International Search Report (PCT/ISA/210) with 0 document(s).</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A FIRST preliminary amendment.</p> <p>14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input checked="" type="checkbox"/> Other items or information:</p> <p> 1.) International Preliminary Examination Report (PCT/IPEA/409)</p> <p> 2.) One (1) Sheet of Formal Drawing</p>					

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
09, 980211		PCT/EP00/04588		3868-0103P	

21. ☒ The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):

Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. **\$1,040.00**

International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **\$890.00**

International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO. **\$740.00**

International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4). **\$710.00**

International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4). **\$100.00**

ENTER APPROPRIATE BASIC FEE AMOUNT =

Surcharge of **\$130.00** for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	7 - 20 =	0	X \$18.00	\$	0.00
Independent Claims	2 - 3 =	0	X \$84.00	\$	0.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable) Yes			+ \$280.00	\$	280.00
TOTAL OF ABOVE CALCULATIONS =				\$	1300.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	0.00
SUBTOTAL =				\$	1300.00
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	0.00
TOTAL NATIONAL FEE =				\$	1300.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	0.00
TOTAL FEES ENCLOSED =				\$	1300.00
				Amount to be:	
				refunded	\$
				charged	\$

CALCULATIONS

PTO USE ONLY

a. ☒ A check in the amount of \$ **1300.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account. No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2448.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to:

Birch, Stewart, Kolasch & Birch, LLP or Customer No. 2292

P.O. Box 747

Falls Church, VA 22040-0747

(703) 205-8000

Date: November 30, 2001

By
James M. Slattery, #28,380

PATENT
3868-0103P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: SCHUMANN, Klaus et al.
Int'l. Appl. No.: PCT/EP00/04588
Appl. No.: New Group:
Filed: November 30, 2001 Examiner:
For: SUBSTRATE SECTIONS HAVING INCREASED
STORAGE STABILITY DURING THEIR
STORAGE IN A BAG PACKAGE, AND
PROCESS FOR THEIR MANUFACTURE

PRELIMINARY AMENDMENT

BOX PATENT APPLICATION

Assistant Commissioner for Patents
Washington, DC 20231

November 30, 2001

Sir:

The following Preliminary Amendments and Remarks are respectfully submitted in connection with the above-identified application.

AMENDMENTS

IN THE SPECIFICATION:

Please amend the specification as follows:

Before line 1, insert --This application is the national phase under 35 U.S.C. § 371 of PCT International Application No. PCT/EP00/04588 which has an International filing date of May 20, 2000, which designated the United States of America.--

REMARKS

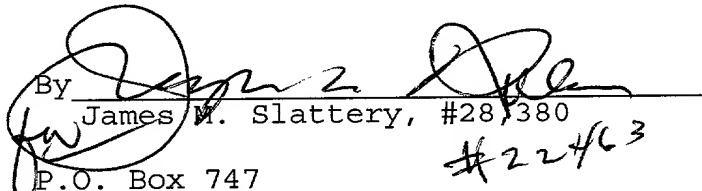
The specification has been amended to provide a cross-reference to the previously filed International Application.

An early and favorable first action on the merits is earnestly solicited.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
James M. Slattery, #28,380

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JMS/rem
3868-0103P

1/PRTS

09/980211
JCTU Rec'd PGT/PTO 30 NOV 2001

Substrate sections having increased storage stability
during their storage in a bag package, and process for
their manufacture

The invention relates to substrate sections which have been rendered pressure-sensitive adhesive and are sealed in bags so as to be protected against loss of active substance, the pressure-sensitive adhesive surface of which is covered by a carrier layer which at least partially projects beyond the said substrate sections and is divided by an incision, thus forming a release aid, through which incision pressure-sensitive adhesive may leak out in cold flow during storage and may cause agglutination with the bag.

It is known how to manufacture and use flat-shaped pressure-sensitive adhesive substrate sections. These may be, for example, active substance-containing transdermal therapeutic systems. If such systems contain volatile components, for example as active agents, there results the necessity of protecting the substrate sections which have been provided with these components against evaporation of the volatile components during the time span between manufacture and use, that is, during their storage up to their application.

This is achieved, for example, by providing the pressure-sensitive adhesive substrate sections with a detachable carrier layer so as to protect their pressure-sensitive adhesive surface and subsequently sealing the sections in a bag surrounding the same on all sides. Here it is convenient for the carrier layer to project beyond the pressure-sensitive adhesive surface of a substrate section so as to, on the one hand, facilitate the peeling of the carrier layer off the substrate layer prior to use, and, on the other hand, prevent the substrate sections from sticking to the package surfaces as a result of pressure-

sensitive adhesive material leaking in cold flow. When the package is open only at one side, such sticking would make removing the laminate more difficult or even render it impossible.

To eliminate this problem, it has already been proposed to provide an incision in the detachable carrier layer, which results in easier detachment of the carrier layer and enables application of the pressure-sensitive adhesive substrate sections to the site of application in a patient. A disadvantage of this measure results from the fact that during storage of the packaged substrate sections it is still possible for the pressure-sensitive adhesive to leak out at the cutting edge of the detachable carrier layer by way of cold flow, it may thus cause extremely disadvantageous sticking of the sections to the surfaces of the package, so that withdrawing the laminate from a package which is open at one side is made even more difficult or impossible.

It is the object of the present invention to provide, in a substrate section of the kind mentioned in the introductory part of Claim 1, an embodiment of the carrier layer provided with a releasing aid, by means of which embodiment the leaking-out of pressure-sensitive adhesive in cold flow can be prevented easily and with simple means, thus facilitating easy withdrawal of substrate sections from a package which is open only at one side.

This object is achieved by the invention in a substrate section of the kind mentioned at the beginning hereof by the fact that to increase the storage stability the carrier layer is configured with two carrier layer sections which overlap each other in the area where they are joined together, preventing the leaking-out of adhesive.

To great advantage, by means of this surprisingly simple embodiment of the carrier layer, the leakage of adhesive and thus any sticking to the packaging material is prevented, and the removal of the laminate when the package is open only at one side is facilitated without difficulty, while the detachability of the carrier layer from the substrate section remains undiminished.

A process for forming substrate sections comprising carrier layer sections, which carrier layer sections project beyond the said substrate sections and form a region of overlap, is characterized in that the said carrier layer sections are supplied with the pressure-sensitive adhesive substrate sections via a dispensing process, for example, according to WO 92/17237, after the carrier layer sections have been overlapped.

Further details, features and advantages of the invention will become apparent from the following explanation of an embodiment example represented schematically in the drawing.

Fig. 1 shows the substrate layer 1 in cross-section, comprising a backing layer 5 and a matrix 6 connected thereto. Said matrix may either be comprised entirely of a pressure-sensitive adhesive material or be rendered pressure-sensitive adhesive on its application surface by providing it with a pressure-sensitive adhesive layer (not shown). The pressure-sensitive adhesive surface or the pressure sensitive adhesive-rendered matrix 6, respectively, is covered by a carrier layer which projects beyond said matrix 6 at least partially and which according to the invention is configured with two carrier layer sections 2,3 which overlap each other in the region where they are joined.

Due to the fact that the carrier layer sections 2, 3 project beyond the matrix 6 at the side edges 7, 8 in a

manner known per se, in the possible case of adhesive leaking out, any sticking to the package bag is reliably prevented.

On account of the fact that the carrier layer 2,3, which is assembled in two parts for reasons of better detachability, is configured with a region of overlap 4, the said carrier layer prevents, also in this region, the leaking-out of pressure-sensitive adhesive in cold flow during a prolonged storage.

One embodiment provides for one of the carrier layer sections 2 to be wider than the other section 3 by the amount of the overlap 4.

However, one may also take the measure of configuring both carrier layer sections 2, 3 to be wider, by an amount of half of the overlap, than half the width dimension of an undivided carrier layer 1.

Furthermore the region of overlap 4 may be placed either centrally or eccentrically on the substrate section 1, without diminishing its function as a detachment aid. This measure facilitates manufacture and its control.

A process for forming substrate sections 1 comprising carrier layer sections 2, 3 which project beyond the said substrate sections and form a region of overlap 4 is characterized in that the carrier layer sections 2, 3 are supplied with the pressure-sensitive adhesive substrate sections 1 after the said carrier layer sections 2, 3 have been overlapped.

The solution according to the present invention is surprisingly simple and optimally solves the task posed at the beginning hereof.

C L A I M S

1. Substrate sections which have been rendered pressure-sensitive adhesive and sealed in bags so as to be protected against loss of active substance, the pressure-sensitive adhesive surface of which is covered by a carrier layer which projects at least partially beyond said substrate sections and is divided by an incision, thus forming a detachment aid, through which incision adhesive may leak out in cold flow during storage and may cause the substrate section to stick to the bag, characterized in that in order to increase storage stability by avoiding leakage of pressure-sensitive adhesive, the carrier layer is configured with two carrier layer sections which overlap each other in the region where they are joined.

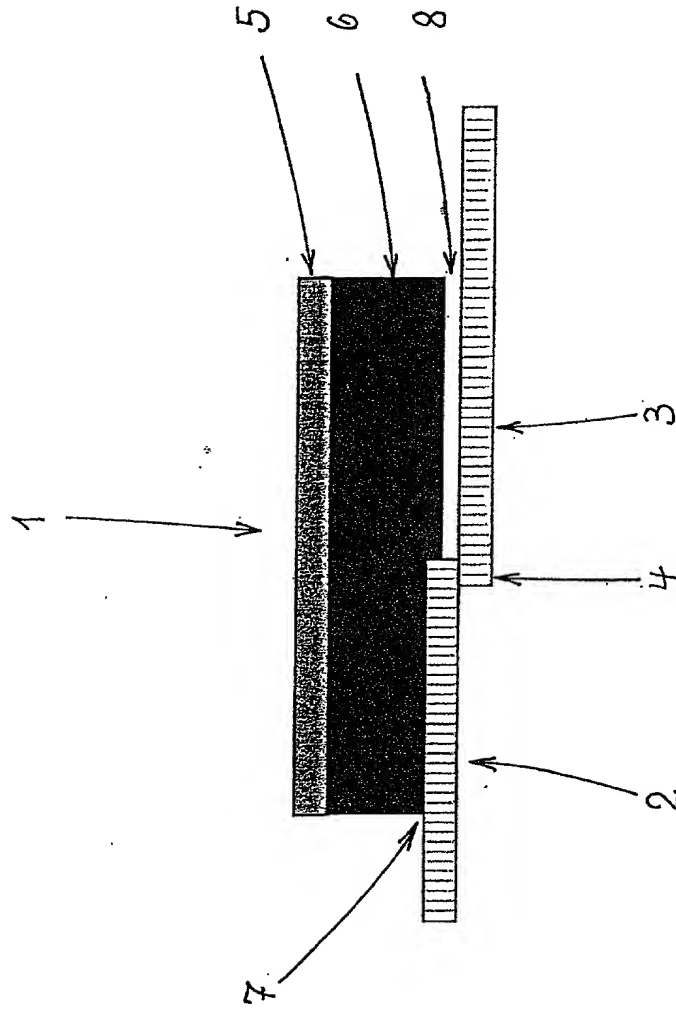
2. Substrate section according to Claim 1, characterized in that one of the carrier layer sections is wider than the other section by the amount of the overlap.

3. Substrate section according to Claim 1, characterized in that both carrier layer sections are, by the amount of half the overlap, wider than half the width dimension of an undivided carrier layer.

4. Substrate section according to Claims 1 to 3, characterized in that the region of overlap is positioned centrally or eccentrically on the substrate section.

5. Process for forming substrate sections comprising carrier layer sections projecting beyond the substrate sections and forming a region of overlap, characterized in that the pressure-sensitive adhesive substrate sections are supplied via a dispensing process to the carrier layer sections after the latter have been overlapped.

FIG. 1



Attorney Docket No.

3868-0103P

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Telephone: (703) 205-8000 • Facsimile: (703) 205-8050**PLEASE NOTE:
YOU MUST
COMPLETE THE
FOLLOWING****COMBINED DECLARATION AND POWER OF ATTORNEY
FOR PATENT AND DESIGN APPLICATIONS**

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated next to my name; that I verily believe that I am the original, first and sole inventor (if only one inventor is named below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Substrate sections having increased storage stability during their storage in a bag package, and process for their manufacture.

Insert Title:

Fill in Appropriate
Information -
For Use Without
Specification
Attached:

the specification of which is attached hereto. If not attached hereto,
the specification was filed on _____ as
United States Application Number _____;
and amended on _____ (if applicable) and/or
the specification was filed on May 20th, 2001 as PCT
International Application Number PCT/EP 00/04588;
amended under PCT Article 19 on May 16th, 2001 (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56. I do not know and do not believe the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representative or assigns more than twelve months (six months for designs) prior to this application, and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns, except as follows.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)**Priority Claimed**Insert Priority
Information:
(if appropriate)

<u>199 25 338.2</u> (Number)	<u>DE</u> (Country)	<u>06.02.1999</u> (Month/Day/Year Filed)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
_____ (Number)	_____ (Country)	_____ (Month/Day/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____ (Number)	_____ (Country)	_____ (Month/Day/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____ (Number)	_____ (Country)	_____ (Month/Day/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below.

Insert Provisional
Application(s):
(if any)

_____ (Application Number)	_____ (Filing Date)
_____ (Application Number)	_____ (Filing Date)

All Foreign Applications, if any, for any Patent or Inventor's Certificate Filed More than 12 Months (6 Months for Designs) Prior to the Filing Date of This Application:

Insert Requested
Information:
(if appropriate)

Country	Application Number	Date of Filing (Month/Day/Year)
_____	_____	_____
_____	_____	_____

I hereby claim the benefit under Title 35, United States Code, §120 of any United States and/or PCT application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States and/or PCT application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to the patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Insert Prior U.S.
Application(s):
(if any)

_____ (Application Number)	_____ (Filing Date)	_____ (Status - patented, pending, abandoned)
_____ (Application Number)	_____ (Filing Date)	_____ (Status - patented, pending, abandoned)

Page 1 of 2
(Rev. 06/2001)

Attorney Docket No.

I hereby appoint the practitioners at **CUSTOMER NO. 2292** as my attorneys or agents to prosecute this application and/or an international application based on this application and to transact all business in the United States Patent and Trademark Office connected therewith and in connection with the resulting patent based on instructions received from the entity who first sent the application papers to the practitioners, unless the inventor(s) or assignee provides said practitioners with a written notice to the contrary:

Send Correspondence to:

BIRCH, STEWART, KOLASCH & BIRCH, LLP or **CUSTOMER NO. 2292**

P.O. Box 747 • Falls Church, Virginia 22040-0747

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PLEASE NOTE:
YOU MUST
COMPLETE
THE
FOLLOWING:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of First
or Sole Inventor:
Insert Name of
Inventor
Insert Date This
Statement is Signed

Insert Residence
Insert Citizenship

Insert Post Office
Address

Full Name of Second
Inventor, if any:
see above

Full Name of Third
Inventor, if any:
see above

Full Name of Fourth
Inventor, if any:
see above

Full Name of Fifth
Inventor, if any:
see above

Full Name of Sixth
Inventor, if any:
see above

GIVEN NAME/FAMILY NAME Klaus SCHLIMM	INVENTOR'S SIGNATURE 	DATE* 18.01.02
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GIVEN NAME/FAMILY NAME Christian VON FALKENHAUSEN	INVENTOR'S SIGNATURE 	DATE* 18.01.02
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Residence (City, State & Country)		CITIZENSHIP
MAILING ADDRESS (Complete Street Address including City, State & Country)		
GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Residence (City, State & Country)		CITIZENSHIP
MAILING ADDRESS (Complete Street Address including City, State & Country)		
GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Residence (City, State & Country)		CITIZENSHIP
MAILING ADDRESS (Complete Street Address including City, State & Country)		

*DATE OF SIGNATURE